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By _____
(Signature of person mailing)

Patricia Litchfield
(Typed or printed name of person)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICATION OF: Leah E. Appel, et al.

APPLICATION NO.: 09/745,095

FILING DATE: December 20, 2000

TITLE: Hydrogel-Driven Drug Dosage Form

Examiner: S. Gollamudi

Group Art Unit: 1616

Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

Sir:

PRE-APPEAL BRIEF REQUEST FOR REVIEW

This Pre-Appeal Brief Request for Review (the "Request") is being filed to request review of the Final Office Action dated March 15, 2006. No amendments are being filed with this request. This request is being filed with a notice of appeal. The review is requested for the reasons stated in the attached sheets.

A three month extension of time is also being submitted herewith, thereby extending the term for response to September 15, 2006.

REMARKS

Preliminary Comments – The Invention

Claims 2, 7-9, 12-32, 44, 49-51, 56-57, 63, 65-81, 88-97, 101, 103-108, 120-122, 124, and 130-131 are currently pending in the application.

Applicants' invention solved a particular problem encountered when trying to design an osmotic tablet for delivery of a low-solubility drug. Osmotic dosage forms function by extruding a drug-containing formulation through an orifice in the dosage form, typically a laser-drilled hole. In the instant invention a problem arose out of the fact that, in order to deliver low-solubility drugs, a drug entraining agent was necessary because the drug is extruded as a viscous suspension due to its low solubility. The additional mass of the entraining agent necessitated using a highly swelling material such as sodium starch glycolate or croscarmellose sodium to push the drug composition out of the dosage form. These highly swelling materials, in turn, presented a further, separate problem in that the highly swelling materials made the formulation difficult to compress

into tablets of sufficient strength that don't chip or break apart extensively during the manufacturing process. See, for example, page 30, lines 31-33 of the application where applicants highlighted the problem.

The aforementioned problem is by no means trivial from a manufacturing perspective in that, although a highly swelling material for use in the push layer is desirable for its ability to completely or nearly completely extrude the drug composition, such highly swellable materials are generally friable and, as a consequence, contribute to chipping and breakage.

Thus, the inventors solved the problem of delivering a low-solubility drug while maintaining sufficient tablet strength by (1) using an entraining agent (2) selecting highly swelling materials for the push layer and (3) adding a tableting aid to ease compression. The swelling materials and tableting aids are specifically recited in the claims.

Herein, "Office Action" is abbreviated as "OA".

The Rejections And Applicants' Traversal

All of the claims, with the exception of claim 57, have been rejected under 35 USC §103(a) over Wong in view of Stevens, optionally further in view of Park. Distilling the rejection into its most basic elements, the reasoning underlying the Wong v/ Stevens rejection is (1) Wong discloses an osmotic dosage form but doesn't teach Applicants' parameters such as the required swelling ratio and core strength, nor the swelling agents or the amount of tabletting aids (3/15/06 OA at Page 4); (2) Stevens discloses a (non-osmotic) delivery device that can incorporate Applicants' swelling agents and tabletting aids, including those having a suitable swelling ratio; in example 10 Stevens discloses a swelling agent containing a combination of sodium starch glycolate (EXPLOTAB) and microcrystalline cellulose (AVICEL), materials specified in Applicants' claim 2.

Applicants submit that the rejection should be reversed because Wong and Stevens are not properly combinable. The following reasons apply:

1. The combination of Wong and Stevens is untenable because the dosage form in Wong operates in a manner opposite to the dosage form in Stevens. Wong discloses an osmotic dosage form which, as is well known and recognized in the art, functions by extruding the core material out of one or more orifices. Osmotic devices, in use, are designed to stay together, not to come apart. Stevens discloses a capsule/tablet device containing an expandable portion that pushes two halves of his device apart. Stevens, column 2, line 35 to column 3, line 4. It is untenable to select the expandable element from Stevens, a device that is specifically designed to blow up, and combine it with Wong, a device that must remain intact in order to function correctly.

2. The Examiner contends that Stevens discloses tablets as well. 3/15/06 OA at page 5, first line. There is no basis to believe that any embodiment referred to by Stevens as a

tablet is not designed to come apart like the capsule embodiment, as supported by the remainder of the Stevens disclosure.

3. It would be totally arbitrary for one of ordinary skill in the art to zero in on a particular swelling agent in Stevens' over any other swelling agent (or combination of swelling agents) that Stevens also discloses, but that would be outside the requirements of Applicants' claim 2, and that would not provide the advantages that Applicants specifically sought in respect of manufacturing tablets.

4. The examiner has consistently taken the position that tablets and capsules are generally the same. See the 6/3/05 OA at page 9, last paragraph. Applicants submit that the Examiner's contentions are misplaced. It is well known in the art that tablets are formed by compressing the materials to a required hardness, and then coating them. It is necessary that tablets are compressed to a relatively high strength so that the tablets remain intact during the coating process. In distinct contrast, capsules are formed using filling machines. There is no need for the contents to be of a particular strength, since the capsule wall, or coating, is preformed. There is no reason to consider the problem of capsule breakage or chipping as there is for tablets.

The Examiner contended that it would be obvious to use the swelling agents of Stevens simply because they are highly swelling. 6/3/05 OA at page 7, first full paragraph. The Examiner contended that "...the Examiner maintains her position since Wong's expandable excipient and Stevens expandable excipient function in a similar manner, i.e. to swell and push the active out of the dosage form." Office Action of June 3, 2005 at page 9, bottom four lines. Applicants disagree with this position. All of the many swelling agents recited in Stevens presumably function to swell and push active out of the dosage form. But, that begs the question of why, in the absence of a motivation for doing so, would one of ordinary skill choose the swelling agent of example 10 over any of the other swelling agents also disclosed in Stevens that are outside the scope of Applicants' claims, **for use as the swellable layer in an osmotic tablet**, a device different from Stevens. Even though all of the swelling agents in Stevens presumably function to push out active, the great majority of those swelling agents are outside Applicants claims. As Stevens is directed to dosage forms that come apart, Stevens provides no motivation for choosing any one swelling agent over any other **for use in a tablet** designed to stay together.

The Examiner cited Park as a further optional reference in addition to Wong and Stevens, arguing that Park discloses that disintegrants provide mechanical strength to hydrogels and, therefore, that this disclosure supplies the motivation to include Park in with the Stevens/Wong combination. 3/15/06 OA at pages 6 and 7. Park actually teaches away from Applicants' invention, however. Park is concerned with a hydrogel used as a gastric retention device. The mechanical strength referred to in Park is the strength of his swollen hydrogel, not a tablet, so that the hydrogel will remain intact within the stomach to function as a gastric retention device.

The very disintegrant (sodium starch glycolate) referred to by the Examiner (3/15/06 OA, page 6, first 6 lines and page 7, last seven lines) as being beneficial for imparting increased mechanical strength to Park's hydrogel is also a highly swelling material that caused a problem to Applicants - - increased difficulty in making a compressed tablet. That problem in turn necessitated Applicants' solution - - the use of a defined tabletting aid to increase tablet strength. It is untenable to conclude obviousness from Park's beneficial use of sodium starch glycolate to increase hydrogel strength when the very same material is what caused a problem that Applicants needed to solve through the use of a separate tableting aid that increases tablet strength. Park does not disclose using Applicants' tableting aids and swelling materials together in a tablet, and presumably Park would not have needed to use such aids since his use of sodium starch glycolate led to a benefit, not a problem.

Claim 57 continues to be rejected over Wong et al. in view of Stevens et al, optionally in further view of Park, and in further view of the Jim Kling article. Kling was cited simply for its teaching of Viagra® as a drug for hypertension or erectile function. Noting that claim 57 depends directly from claim 2, the rejection should be reversed on the basis that it does nothing to cure the deficiencies of Wong, Stevens and Park discussed above.

Double Patenting

Claims 2, 7-9, 12, 15-32, 44, 49-51, 56, 57, 63-81, 88-97, 101, 103-108, 118-122, 124, 130, 131 has been rejected for obviousness-type double patenting over the claims of US 6,899,896.

Applicants submit the issue of double patenting is moot as Applicants intend to submit a suitable terminal disclaimer. It is thus respectfully submitted that the above issues relating to prior art are the only issues that need to be addressed pursuant to this pre-appeal brief request.

In view of the foregoing arguments, it is respectfully requested that the rejections under 35 USC §103 be reversed, and that the double patenting rejection be deferred as Applicants intend to resolve the issue by submitting a terminal disclaimer.

Respectfully submitted,

Date: Sept. 15, 2006

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